

REMARKS

Claims 1, 2, 11, 12, 15-17, 22 and 30-34 are now present in this application. Claims 1, 22, 30 and 32 are independent. Claims 3-10, 13-14, 18-21 and 23-29 have been canceled.

Claims 1, 2, 9-11, 15-16, 19 and 22 have been amended to be limited to the combination of GF120918 and at least one pharmaceutically active compound, wherein the pharmaceutically active compound is selected from the group consisting of camptothecin and a camptothecin derivative.

Claims 33-34 have been amended to remove a typographical error.

No new matter has been added to the disclosure.

Reconsideration of this application, as amended, is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 5, 6, 13, 15-17, 22, 32 and 33 stand rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse the rejection.

The rejection under 35 U.S.C. 112, first paragraph is based on the allegation that the claims are so broadly written as to encompass non-enabled subject matter. The Examiner finds that the specification enables the skilled artisan to make and/or use the invention limited to the combination of GF120918 and topotecan (a camptothecin derivative), but the Examiner alleges that the specification does not enable the skilled artisan to make and/or use the invention which is a combination of GF120918 and **any** pharmaceutically active compound.

In response, Applicants have canceled some subject matter from the claims. The current claims recite the combination of GF120918 and at least one pharmaceutically active compound, wherein the pharmaceutically active compound is selected from the group consisting of camptothecin and a camptothecin derivative. Applicants reserve the right to pursue the canceled subject matter in one or more Continuation Applications at a later date.

Applicants respectfully submit that the claims, as currently amended are sufficiently enabled by the specification, such that the rejection under 35 U.S.C. §112, first paragraph is not tenable.

First, the camptothecin (derivatives) are known pharmaceuticals. However, a problem associated with their use is the fact that their bioavailability after oral administration is limited by

a multi-drug resistant mechanism associated with the protein called Breast Cancer Resistance Protein or BCRP (also known as MXR or ABCP). A number of recent publications have illustrated that this protein is also a drug resistance related protein. A list of such disclosures are provided on page 4, lines 1-6 of the specification. Hence, the present inventors have through ingenuity identified that GF120918 counters the deleterious effects of BCRP thereby improving the bioavailability of the camptothecin (derivative).

Second, the scope of the active compounds is readily determinable from the specification. As mentioned above, the claims have been limited to the combination of GF120918 and at least one pharmaceutically active compound, wherein the pharmaceutically active compound is selected from the group consisting of camptothecin and a camptothecin derivative. With respect to the scope of the term “camptothecin derivative”, the Examiner’s attention is directed to the disclosure at page 6, lines 22-26 of the specification for guidance in the types of structures (including their inherent properties) that would be encompassed by this term. Accordingly, the skilled artisan would understand the scope of the active species used in the practice of the present invention.

Third, the specification provides guidance to the artisan as to how to improve the bioavailability of the camptothecin (derivative) with GF120918, as presently claimed. Dosage amounts are discussed at page 10, last paragraph.

Also, the experiments in the specification show that GF120918 can and does improve the bioavailability of the camptothecin (derivative). Example 1 shows that GF120918 is effective in improving the cytotoxicity of a variety of drugs to human ovary-cancer cell-lines IGROV1 and T8. Example 2 shows that GF120918 improves the oral availability of the camptothecin derivative, topotecan, in the mouse model. Lastly, Example 3 shows that GF120918 improves the oral availability of the camptothecin derivative, topotecan, in humans.

Accordingly, should the Examiner apply the *balancing* test for enablement by weighing the effect of each of the factors set forth in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), it is clear that the currently claimed invention, which is drawn to the combination of GF120918 and at least one pharmaceutically active compound, wherein the pharmaceutically active compound is selected from the group consisting of camptothecin and a camptothecin derivative, is sufficiently enabled so that the skilled artisan could practice the present invention without

undue burden. As such, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Drawings

It is noted that this application has been filed with two sheets of formal drawings. However, the USPTO has not indicated if the drawings are acceptable. In the next communication, the Examiner is requested **a second time** to indicated whether the drawings are acceptable.

Information Disclosure Statements

Two Information Disclosure Statements have been timely filed on October 25, 2004 and May 3, 2005. Applicants respectfully request that the Examiner considers the references cited therein, and forwards to Applicants copies of the signed and initialed PTO-1449 forms with the next communication.

Conclusion

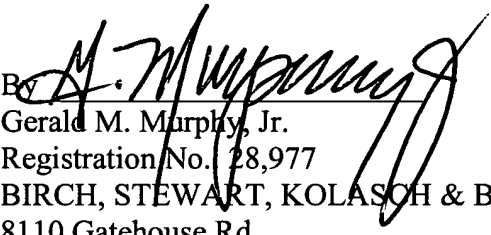
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact **Garth M. Dahlen, Ph.D., Esq.** (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,


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